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DOCKET NO.: PRES06-00163

Sustomer No.: 23990

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

RONALD A. SCHACHAR

U.S. Serial No.

09/556,143

Filing Date

April 21, 2000

Examiner

David M. Shay

Group Art Unit

3739

Title

SEGMENTED SCLERAL BAND FOR TREATMENT OF

PRESBYOPIA AND OTHER EYE DISORDERS

MAIL STOP AF Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

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TECHNOLOGY CENTER R3700

Sir:

RESPONSE TO FINAL OFFICE ACTION

In response to a final Office Action dated March 24, 2003, the Applicant respectfully requests the Examiner to reconsider (1) the Examiner's objection to the Applicant's Amendment dated December 23, 2002 as having allegedly introduced new matter; and (2) the Examiner's withdrawal of Claims 45-48 from consideration as having allegedly been directed to a non-elected invention, and (3) the Examiner's rejection of Claims 31-44 under 35 U.S.C. § 102(b). The Applicant respectfully requests an Advisory Action.

Applicant is submitting a Notice of Appeal concurrently herewith.

<u>ARGUMENTS</u>

1. Request to Reconsider New Matter Rejection

35 U.S.C. §132(a) provides, in pertinent part, that "No amendment shall introduce new matter into the disclosure of the invention." The Examiner objected to the Applicant's Amendment of December 23, 2002 for allegedly adding new matter. Specifically, the Examiner asserted that "The added material which is not supported by the original disclosure is as follows: the description of Figures 10, 11; the disclosure running from line 21 on page 22 through the end of page 25 of substitute specification; and newly submitted Figures 10 and 11. Applicant is required to cancel the new matter in the reply to this Office Action." (Page 2, Office Action dated March 24, 2003).

The Allegedly New Matter Was Present in the Original Patent Application by Incorporation by Reference from United States Patent No. 5,354,331. The Incorporation by Reference is on Page 9, Lines 3-5 of the Original Specification.

The allegedly new matter was present in the original patent application by the incorporation by reference of United States Patent No. 5,354,331 to *Schachar* dated October 11, 1994. (Page 9, Lines 3-5 of Original Specification) (Page 10, Lines 11-13 of Substitute Specification). The present patent application is a continuation of co-pending United States Patent Application Serial No. 09/032,830 filed on March 2, 1998 (the "830 Application"). The '830 Application is a continuation-in-part of then co-pending United States Patent Application Serial No. 08/462,649 filed June 5, 1995, now United States Patent No. 5,722,952 (the "649 Application"). The '649 Application was a co-pending divisional of United States Patent Application Serial No. 08/139,756, filed, October 22, 1993, now U.S. Patent No. 5,489,299 (the "756 Application"). The '756

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Application was a co-pending divisional of United States Patent Application Serial No. 07/913,486, filed on July 15, 1992, now United States Patent No. 5,354,331 (the "486 Application"). The '830 Application also incorporated by reference the '486 Application, now United States Patent No. 5,354,331, into the body of the '830 Application.

The Applicant respectfully asserts that Figure 10 and Figure 11 clarify the original disclosure but do not add new matter. The matter disclosed in Figure 10 and Figure 11 is supported by the material incorporated by reference from United States Patent No. 5,354,331 to *Schachar*. In particular, the allegedly new matter (i.e., description of figures 10, 11; the disclosure running from line 21 on page 22 through the end of page 25 of substitute specification; and newly submitted figures 10 and 11) is supported by the text of United States Patent No. 5,354,331 to *Schachar* from Column 7, Line 43 through Column 8, Line 45. This portion of United States Patent No. 5,354,331 clearly describes the concept of using laser radiation to weaken the sclera of the eye in the region overlying the ciliary body in order to increase the effective working distance of the ciliary muscle of the eye.

The Applicant respectfully submits that no new matter has been added to the patent application by the Amendment of December 23, 2002. The Applicant therefore also respectfully submits that the Amendment of December 23, 2002 is not objectionable under 35 U.S.C. §132. The Applicant respectfully requests that the Examiner reconsider the requirement to cancel the allegedly new matter. The Applicant respectfully requests the Examiner to withdraw the requirement to cancel the allegedly new matter.

2. Request to Reconsider Election Requirement Rejection

37 U.S.C. §1.142 provides that:

- (a) If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant to elect an invention to which the claims will be restricted, this official action being called a requirement for restriction (also known as a requirement for division). Such requirement will normally be made before any action on the merits; however, it may be made at any time before final action.
- (b) Claims to the invention or inventions not elected, if not canceled, are nevertheless withdrawn from further consideration by the examiner by the election, subject however to reinstatement in the event the requirement for restriction is withdrawn or overruled.

In the Office Action dated March 24, 2003 the Examiner characterized Claims 45-48 as being directed to an invention that is independent or distinct from the invention originally claimed. The Examiner withdrew Claims 45-48 from consideration as being directed to a non-elected invention (Page 2, Office Action dated March 24, 2003).

The Applicant respectfully traverses the Examiner's characterization of Claims 45-48. When one compares the subject matter of Claims 45-48 with the subject matter of Claims 31-44 it is clear that Claims 45-48 are <u>not</u> directed to an invention that is "independent or distinct" from the invention claimed in Claims 31-44. Both sets of claims (i.e., Claims 31-44 and Claims 45-48) are directed to increasing the effective working distance of the ciliary muscle of the eye by using laser radiation to weaken the sclera of the eye in the region of the ciliary body.

The Examiner stated that Claims 45-46 were directed to an invention that is independent or distinct from the invention originally claimed "for the following reasons: the apparatus could be used

for a substantially different method, such as transmyocardial revascularization." (Page 2, Office Action of March 24, 2003) (Emphasis added).

Claims 45-46 are directed to a <u>method</u> and not to an apparatus. There is no apparatus claimed in Claim 45 or in Claim 46. There is no apparatus that could be used for "a substantially different method, such as transmyocardial revascularization." The Appellant respectfully submits that the method claimed in Claims 45-46 can not be used for "a substantially different method, such as transmyocardial revascularization." Claims 45-46 are therefore not directed to an invention that is "independent or distinct" from the invention claimed in Claims 31-44.

The Appellant respectfully requests reconsideration of the Examiner's restriction requirement for Claims 45-48. The Appellant respectfully petitions for a review of the restriction requirement and respectfully requests that the restriction requirement for Claims 45-48 be withdrawn.

3. Request to Reconsider Anticipation Rejection

On Page 2 of the March 24, 2003 Office Action the Examiner rejected Claims 31-44 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 4,391,275 to Fankhauser et al. (hereafter "Fankhauser"). Applicant respectfully traverses this rejection by the Examiner. Independent Claim 31 and independent Claim 40 read as follows:

31. A laser operable to <u>weaken the sclera of an eye</u> in the region of the ciliary body with laser irradiation to thereby <u>increase the effective</u> <u>working distance of the ciliary muscle of the eye</u>. (Emphasis added).

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40. A method of operating a laser to treat one of presbyopia, hyperopia, primary open angle glaucoma and ocular hypertension, said method comprising the step of irradiating the sclera of the eye in the region of the ciliary body to thereby weaken the sclera of the eye and increase the effective working distance of the ciliary muscle of the eye. (Emphasis added).

A determination of anticipation, with respect to Claim 31 or with respect to Claim 40, requires that each feature claimed therein be described in *Fankhauser* in sufficient detail to enable one of ordinary skill in the art to make and practice the claimed invention. Applicant respectfully asserts that the above emphasized limitations of Claim 31 and Claim 40 are not disclosed, suggested or even hinted at in the *Fankhauser* reference. In particular, Claim 31 and Claim 40 each recite the limitation of "weakening the sclera of the eye with laser irradiation to increase the effective working distance of the ciliary muscle of the eye." This limitation is not disclosed, suggested, or even hinted at in the *Fankhauser* reference.

Fankhauser discloses a method that uses laser radiation to perforate the tissues of an eyeball in order to reduce an increased level of intra-ocular pressure in the eye due to glaucoma. There is nothing in the Fankhauser reference that discloses, suggests or even hints at the invention disclosed and claimed by the Applicant. Simply stated, Claim 31 and Claim 40 are not anticipated by the Fankhauser reference. The Appellant respectfully submits that Claim 31 and Claim 40 are patentable.

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As between Claim 40 and the *Fankhauser* reference, the Applicant submits that independent Claim 45 and independent Claim 46 contain limitations analogous to those found in Claim 40. For the reasons given above, the Applicant respectfully asserts that Claim 45 and Claim 46 are also patentable over the *Fankhauser* reference.

Applicant notes that Claims 32-39 depend from Claim 31 and contain all of the unique and novel limitations contained in Claim 31. This being the case, Claims 32-39 are also patentable over the *Fankhauser* reference. Also, Claims 41-44 depend from Claim 40 and contain all of the unique and novel limitations contained in Claim 40. This being the case, Claims 41-44 are patentable over the *Fankhauser* reference.

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SUMMARY

The Applicant believes that this Application is in condition for allowance. If any outstanding issues remain, or if the Examiner has any further suggestions for expediting prosecution of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at wmunck@davismunck.com.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

DAVIS MUNCK, P.C.

P. O. Drawer 800889 Dallas, Texas 75380

Tel.: (972) 628-3600 Fax: (972) 628-3616

Email: wmunck@davismunck.com

illiam A. Munck

Registration No. 39,308